

901 E. 233rd Street Carson, California 90745-6204 310/835-8400 Fax 31 0/835-6615

July 8, 1999

Office of Special Nutritionals (HFS-450) Center **for** Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street SW Washington, DC 20204



Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statements:

Three unique muitivitamin formulas for optimal energy and well being

Your Life@ Women's Cycle Multivitamin is a unique combination of three formulas, especially made to coincide with women's special cycles of the month. Designed to be used by women who have a 28-day cycle, are hormonaily regulated, or who use oral contraceptives. All formulas include Soy isofiavones for female support along with extra B-vitamins, which can be lacking from a woman's diet and negatively impacted due to oral contraceptives. Additionally, each individual formula includes special nutrients that will enhance one's health and provide important benefits for the different cycles of the month:

Maintenance Formula -A blend of important ingredients to support women's needs during their regular cycle. Red Raspberry leaf is included for female support.

Premenstrual Formula – Fever-few and Kava Kava have been included along with additional Vitamin K and Vitamin B-6 to support female health during the premenstrual cycle.

Menstrual Formula -To meet special needs that women tend to experience at this time of the month, iron is Included, as well as a special type of "women's" ginseng – notoginseng. Other beneficial ingredients include Feverfew, additional Foiate, Niacin, Molybdenum, Manganese, and Gamma Linoienic acid.

on the following product:

YourLife® Women's Cycle™ MULTIVITAMIN

Very truly yours,

Leiner Health Products

Hany Farag, Director of Regulatory Affairs

cc: William Cochran, Manager of Regulatory Affairs